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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/380,086	11/29/99	PEREZ	P BET-99/0730

000466 HM22/0227
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EXAMINER	
KUBELIK, A	
ART UNIT	**PAPER NUMBER**
1638	12

DATE MAILED: 02/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/380,086	PEREZ ET AL.	
	Examiner	Art Unit	
	Anne Kubelik	1638	

-- The MAILING DATE of this communication appears on th cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *2,4 and 6-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group II (claims 1, 3 and 5; use of a plant with nuclear male sterility for avoiding dissemination of a transgene) in Paper No. 11 is acknowledged. The traversal is on the ground(s) that no lack of unity was found in the PCT and that since a search on all claims was done for the PCT, there would be no burden of search now. This is not found persuasive because an examiner is not bound by the actions of another examiner, particularly one in a foreign patent office. Examiner's analysis of the instant application does not rely on the PCT examination for either searching or for claim analysis.

Additionally, Applicant questions the application of Odell et al (WO 91/09957) as an argument for lack of unity. Applicant asserts while Odell et al teaches a cre-loxP system to eliminate transgenes, they do not mention that this method would prevent dissemination of those same transgenes. However, prevention of dissemination would be an inherent feature of the cre-lox system. Similarly, the method of Oliver et al (WO 96/04393) produces plants that make seed that cannot germinate (pg 9, lines 8-18). Plants whose seed cannot germinate are inherently unable to disseminate transgenes, or any other gene.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1 and 5 are examined to they extent they read on nuclear male sterility.

Specification

3. The abstract of the disclosure is objected to because it contains more than one paragraph and because it incorrectly indicates that there are no figures in the application. Additionally, the

placement of the abstract within the specification is incorrect (see below) Correction is required. See MPEP § 608.01(b).

4. The specification as submitted is missing several parts, including (e), (f), (g), and (h) below. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

5. The specification is objected to for lacking a description of the figures.

6. The specification should be amended to indicate the appropriate SEQ ID NO: after the primer sequences on pg 32, lines 28-29, pg 38, lines 36-37, and pg 39, lines 16-17, per 37 CFR 1.821 (d). The SEQ ID NOs of the sequences in the Figures should also be indicated in the Brief Description of the Drawings. A computer readable form of the sequences should be submitted,

along with a statement that the paper and the computer readable copies are the same, as required by 37 CRF 1.821 through 1.825. See MPEP 2420-2426.

7. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

For example, the attempt to incorporate subject matter into this application by reference to WO 96/33277 is improper because essential material may not be incorporated by reference to a foreign patent.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1, 3 and 5 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, *i.e.*, results in a claim that is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1, 3 and 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to prevention of dissemination of a transgene via use of a nuclear male sterility system, comprising any male sterility gene, any promoter and any other regulatory sequences. The instant specification, however, fails to provide guidance for prevention of dissemination of a transgene.

Prevention of escape of a transgene is unpredictable. Gray et al (1998, Nature 392:653-654) point out that because plants that are male-sterile are still female-fertile, transgenic plants, and thus the transgenes within them, can still escape via seed spillage (pg 654, column 2, paragraph 1); they can still disseminate transgenes via the seed.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate methods for use of nuclear male-sterile plants for prevention of dissemination of transgenes.

12. Claims 1, 3 and 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plasmids contained in microorganisms. If the plasmids contained in the microorganisms are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plasmids contained in the microorganisms are not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the microorganisms. The specification does not disclose a repeatable process to obtain the plasmid contained in the microorganism and it is not apparent if the plasmid is readily available to the public. Thus, a deposit is required for enablement purpose. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,

(e) the deposit will be replaced if it should ever become inviable.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1, 3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Claim 1 is indefinite in its recitation of the word "avoiding." The extent to which dissemination of transgenes is prevented is unclear.

Claim 3 is indefinite for its use of the phrase "a nuclear male sterility." As the noun is missing, it is unclear what the phrase "a nuclear male sterility" is intending to modify. For purposes of examination, it was assumed that the missing noun was either "gene" or "system." Such treatment does not relieve Applicant of the responsibility to respond to this rejection. Dependent claims are included in the rejection.

Claim 5 is not written in proper Markush format. The claim should be in the format "from **the group consisting of** A, B, C and D." It is suggested that the claim be amended to insert --the group consisting of-- after "from". See MPEP 2173.05(h).

15. Claims 1, 3 and 5 provide for the use of a male-sterile plant, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 1, 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al (1992, Plant Mol. Biol. 19:611-622) in view of each of Ellstrand et al (1990, Bioscience 40:438-442) and Nyers et al (1991, J. Cell Biochem 15A:136).

The claims are drawn to the use of nuclear male sterility to avoid dissemination of a transgene.

Paul et al teach a transgene, neomycin phosphotransferase, in pBin19 linked to a nuclear artificial male sterility gene system, consisting of the A9 promoter operably linked to Barnase and the CAMV polyadenylation signal (pg 613, left column, paragraph 2, and Fig 4b) and its transformation into tobacco to produce plants with nuclear male-sterility (pg 617, left column, paragraph 2), they are inherently unable to transmit the neomycin phosphotransferase gene. Paul et al do not teach the use of those plants to avoid transgene dissemination.

Ellstrand et al teach that genetically engineered male sterility can be used to prevent release of engineered genes (paragraph spanning pg 440-441).

Nyers et al that genetic sterility would prevent entry of introduced genes into wild tree populations.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to use the nuclear male-sterility system described in Paul et al and to modify that to avoid dissemination of transgenes as taught by each of Ellstrand et al and Nyers et al. One of ordinary skill in the art would have been motivated to do so because of the risks associated with transfer of transgenes to weeds and wild plants (Ellstrand et al, pg 438, and Nyers et al).

18. Claims 1, 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Worrall et al (1992, Plant Cell 4:759-771) in view of Ellstrand et al (1990, Bioscience 40:438-442) and Nyers et al (1991, J. Cell Biochem 15A:136).

The claims are drawn to the use of nuclear male sterility to avoid dissemination of a transgene.

Worrall et al teach a transgene, neomycin phosphotransferase, in pBin19 linked to a nuclear artificial male sterility gene system, comprising the A3 or A9 tapetum-specific promoters, PR ß-1,3-Glucanase and the CaMV terminator and the transformation of the resulting constructs into the nucleus of tobacco to make plants with nuclear male-sterility (Fig. 1 and pg 761 paragraph spanning the columns). Worrall et al do not teach the use of those plants to avoid transgene dissemination.

Ellstrand et al teach that genetically engineered male sterility can be used to prevent release of engineered genes (paragraph spanning pg 440-441), as discussed above.

Nyers et al that genetic sterility would prevent entry of introduced genes into wild tree populations, as discussed above.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to use the nuclear male-sterility system described in Worrall et al and to modify that to avoid dissemination of transgenes as taught by each of Ellstrand et al and Nyers et al. One of ordinary skill in the art would have been motivated to do so because of the risks associated with transfer of transgenes to weeds and wild plants (Ellstrand et al, pg 438, and Nyers et al).

Conclusion

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached on Monday through Friday, 8:15 am - 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Anne R. Kubelik, Ph.D.
February 23, 2001

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638